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EDWARD J. LYNCH, PATENT ATTORNEY ONE EMBARCADERO CENTER SUITE 562 SAN FRANCISCO, CA 94111			EXAMINER	
			TOWA, RENE T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/790,416	Applicant(s) BURBANK ET AL.
	Examiner RENE TOWA	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 March 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,29,31-33 and 40-51 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1, 29, 31-33, and 40-51 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-546)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No./Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No./Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

1. This Office action is responsive to an amendment filed March 18, 2008. Claims 1, 29, 31-33 and 40-51 are pending. Claims 1, 40, 42 & 45 are amended. No new claim has been added. Claims 2-28, 30 & 34-39 have been cancelled.

Claim Objections

2. Claim 1 is objected to because of the following informalities:

At line 19 of the claim, insert --to-- between "configured" and "extend."

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 1 and 40-51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (US 5,794,626) in view of Tihon et al. (US 5,415,656).

In regards to **claim 1**, Kieturakis discloses a biopsy instrument 5 for retrieving body tissue, having a longitudinal axis and comprising:

an elongated shaft having a longitudinal axis;

a tissue penetrating distal end 45 adapted for tissue penetration; and,

a distal shaft portion proximal to the distal end 45;

an electrosurgical cutting element 10 coupled to the distal shaft portion which is longitudinally disposed on a distal shaft portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to the distal shaft portion, and which is movable in said radially extended position to isolate a

desired intact tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen, and

an encapsulation component 285 configured to extend over the distal shaft portion to encapsulate the isolated tissue specimen and to secure the intact tissue specimen to the distal shaft portion to facilitate removal of the intact tissue specimen from a patient's body along with removal of the instrument (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to **claims 40-44**, Kieturakis discloses an instrument assembly 5 for isolating a tissue specimen from an intracorporeal site, comprising:

a. an elongate shaft 40 which has a longitudinal axis, a tissue penetrating distal end 45 and distal shaft portion proximal to the distal end;

and

b. a tissue cutting component 10 coupled to the distal shaft portion which is radially extendable from a retracted position to an extended position and which is capable of creating a peripheral boundary about the tissue specimen and electrosurgically isolating a desired tissue specimen intact from surrounding tissue at the site; and

c. a tissue collection component 285 coupled to the shaft 40 which is configured to extend over the exterior of the distal shaft portion to encapsulate the isolated tissue specimen from the surrounding tissue at the site (see fig. 12) and

securing the intact specimen to the exterior of the distal portion to facilitate removal of the specimen with removal of the assembly from the patient (see col. 8, lines 28-56);

wherein the tissue collection component 285 is capable of maintaining the encapsulated tissue specimen intact (see fig. 12);

wherein the tissue cutting component 10 is longitudinally disposed on the distal shaft portion;

wherein the tissue cutting component 10 is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen;

wherein both the cutting component 10 and the tissue collection component 285 are movable from a retracted position to an expanded position (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to **claims 45-48**, Keturakis discloses an excisional device 5 for cutting and removing a specimen of breast tissue, comprising:

an elongate shaft 40 having a tissue penetrating distal tip 45, a proximal shaft portion and a distal shaft portion proximal to the distal tip 45;

a tissue cutting component 10 which is coupled to and longitudinally oriented on the distal shaft portion of the shaft, which is configured to cut the specimen of breast tissue from surrounding breast tissue;

a tissue encapsulation component 285 coupled to the distal shaft portion of the shaft 40 which is configured to encapsulate the cut specimen and maintaining the

encapsulated specimen intact, both the cutting component 10 and the tissue encapsulation component 285 being movable from a retracted position to an expanded position;

wherein at least one tissue encapsulation component 285 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position (see figs. 2-3);

wherein the tissue encapsulation component 285 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24;

wherein the tissue encapsulation component 285 and the tissue-cutting component 10 are configured to expand and retract together (see figs. 2-3).

In regards to **claims 49-51**, Kieturakis discloses an instrument 5 for cutting and encapsulating and removing a tissue specimen from a patient's body, comprising:

- a. an elongate shaft 40 which has a tissue penetrating distal end 45, a distal shaft portion proximal to the distal end 45 and a longitudinal axis;
- b. a tissue cutting component 10 which is coupled to and is disposed longitudinally on a distal shaft portion of the distal shaft portion and aligned with the longitudinal axis, which is radially extendable from a retracted position to an extended position, relative to the longitudinal axis, which has an arcuate shape in the extended position and which is movable in the radially extended position about the longitudinal axis to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 2-3 & 12); and

c. an encapsulation component 285, coupled to the distal shaft portion and capable of encapsulating the tissue specimen after it has been isolated from surrounding tissue and removing the tissue specimen from the patient's body intact;

wherein the instrument 5 has a distal tissue-cutting element 45 with a linear cutting surface disposed on the distal end of the shaft 40 to facilitate accessing the tissue specimen within the patient's body;

wherein the encapsulation component 285 has a plurality of encapsulation elements, which are radially extendable from a retracted position to an extended position (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

Kieturakis discloses a system, as described above, that teaches all the limitations of the claims except Kieturakis does not teach an electrosurgical cutting element.

However, **Tihon et al.** disclose an apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; column 1/lines 65-68; column 2/lines 1-5 & 20-31; column 3/lines 21-33; column 5/lines 56-64; column 8/lines 32-41).

In regards to **claims 1, 40, 45 & 49**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system

similar to that of Kieturakis with an electrosurgical cutting step similar to that of Tihon et al. in order to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis (see Tihon et al., column 1/line 65 to column 2/line 5).

5. **Claim 29** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. ('547) in view of Tihon et al. ('656).

Ritchart et al. disclose(s) a method, comprising:

providing a biopsy instrument having a longitudinal axis (see figs. 31-34);

inserting the biopsy instrument comprising a tissue penetrating distal end 152 into the patient's body and advancing the instrument therein until a distal end of the shaft portion is disposed in a tissue region from the tissue specimen is to be taken,

expanding an encapsulating component 150 and moving the expanded component to encapsulate to encapsulate the isolated tissue specimen 138c and securing the tissue specimen to the distal shaft portion to facilitate removal of the tissue specimen from the a patient's body along with removal of the instrument; wherein method comprising proximally withdrawing the instrument with the encapsulated tissue specimen from the patient's body (see figs. 1 & 31-34; column 15/lines 21-45).

Ritchart et al. disclose a method, as described above, that fails to explicitly teach a radially expandable electrosurgical cutting element.

However, Tihon et al. disclose a method and apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an

electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; column 1/lines 65-68; column 2/lines 1-5 & 20-31; column 3/lines 21-33; column 5/lines 56-64; column 8/lines 32-41);

wherein the method comprises radially extending the electrosurgical tissue cutting element so that a portion thereof is radially spaced from the axis of the shaft; energizing the electrosurgical cutting element by delivering radiofrequency energy thereto;

rotating the energized cutting element about the axis while delivering radio frequency energy thereto to cut the tissue and create a peripheral boundary about the tissue specimen so as to isolate the tissue specimen intact from surrounding tissue in the tissue region (see figs. 2 & 8; column 1/lines 65-68; column 2/lines 1-5 & 20-31; column 3/lines 21-33; column 5/lines 56-64; column 8/lines 32-41).

Since it is known to provide biopsy instruments with radially rotatable cutting elements around a tubular body (see elements 32, 34, 36 of fig. 1 of Russin, US 5,795,308), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a method similar to that of Ritchart et al. to include a radially rotatable electrosurgical cutting element to the instrument as taught by Tihon et al. in order to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting

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element permits the convenient application of coagulating power for hemostasis (see Tihon et al., column 1/line 65 to column 2/line 5).

6. **Claims 31-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. ('547) in view of Tihon et al. ('656) further in view of Kieturakis ('626).

Ritchart et al. as modified by Tihon et al. disclose a method, as described above, that fails to explicitly teach a rotating encapsulating element.

However, **Kieturakis** discloses a method for retrieving a tissue specimen from a patient's body, comprising:

inserting into the patient's body an instrument 5 having a distal end 45, a longitudinal axis, and an axially disposed cutting element 10 so that the distal end 45 is disposed in a tissue region from which the tissue specimen is taken;

radially extending the cutting element 10 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5;

rotating the cutting element 10 about the axis to cut the tissue and create a peripheral boundary about the tissue specimen, to isolate the tissue specimen from surrounding tissue in the tissue region; and

encapsulating the isolated tissue specimen before removing the specimen from the patient's body (see column 2/lines 35-60);

wherein the encapsulating step further includes radially expanding at least one encapsulating element 15 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5 and rotating the instrument 5 about its axis so that the at least

one encapsulating element 15 encloses the tissue specimen (see column 2/lines 48-53);

wherein said at least one encapsulating element 15 comprises a plurality of bands which are disposed axially along said instrument 5 (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a method similar to that of Ritchart et al. as modified by Tihon et al. to include an encapsulating step similar to that of Kieturakis in order to facilitate cutting tissue through a controllable rotational force and/or achieve a clean cut.

7. **Claim 33** is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. ('547) in view of Tihon et al. ('656) further in view of Jamshidi (US 3,598,108).

Ritchart et al. as modified by Tihon et al. disclose a method, as described above, that fails to explicitly teach electrosurgically cutting tissue while withdrawing an instrument with the encapsulated tissue specimen from the patient's body.

However, **Jamshidi** discloses a method wherein the instrument is withdrawn while the instrument is energized to cauterize the biopsy track and thereby prevent bleeding thereof (see abstract; col. 1, lines 21-30).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a method similar to that of Ritchart et al. as modified by Tihon et al. to include step of step of energizing the instrument as it is being

withdrawn as taught by Jamshidi in order to cauterize the biopsy track and thereby prevent bleeding and/or seeding of the biopsy track.

Response to Arguments

8. Applicant's arguments filed March 18, 2008 have been fully considered but they are not persuasive. Applicant argues that Kieturakis fails to disclose an encapsulation member configured to secure the specimen to the distal shaft portion. Applicant further argues that Rritchert et al. fail to secure the specimen to the exterior of the distal shaft portion as required in claim 29. These arguments have been considered but have been deemed persuasive.

In regards to the Applicant's argument that Kieturakis fails to disclose an encapsulation member configured to secure the specimen to the distal shaft portion, the Examiner respectfully traverses. The Examiner notes that the term "to encapsulate" is defined by *Webster's II New Riverside University Dictionary (1994)* to mean "to encase in or as if in a capsule"; as such, the Examiner observes that Kieturakis fully teaches a devices, as better depicted in figure 12, wherein the flexors 285 clearly extend over the distal shaft portion to "encase in" the isolated intact tissue specimen in the expanded position (see col. 8, lines 28-56). Similarly, the term "to secure" is defined by *Webster's II New Riverside University Dictionary (1994)* to mean, *inter alia*, "to guard against risk of loss, ...to guarantee, ...to gain possession of: to acquire...to bring about: effect"; as such, the Examiner further notes that Kieturakis fully teaches an apparatus wherein the flexors 285 do "acquire" the intact tissue specimen to the exterior of distal shaft portion through their rotational cutting action in the expanded position (see col. 8, lines 28-56).

As such, the Examiner submits that Kieturakis teaches an apparatus comprising an encapsulation member fully capable of encapsulating and securing a tissue specimen to the exterior of the distal shaft portion as required by the claims.

In regards to the Applicant's argument that Ritchart et al. fail to secure the specimen to the exterior of the distal shaft portion as required in claim 29, the Examiner respectfully traverses. The Examiner has been unable to identify any language from claim 29 or other claims dependent therefrom that recite that the tissue specimen is secured to the exterior of the distal shaft portion. As such, nowhere in claim 29 is there a recitation or a suggestion that the tissue specimen is secured to the exterior of the distal shaft portion as contended by Applicant.

In view of the foregoing, the rejections over Kieturakis and Ritchart et al. are maintained.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,730,726 to Klingenstein discloses an apparatus and method for removing fecal impaction with an encapsulation component.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/

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